

# **EXHIBIT 18**

**(CONTAINS EXCERPTED PAGES)**

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FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

ANESTHETIC AND ANALGESIC DRUG PRODUCTS  
ADVISORY COMMITTEE (AADPAC) MEETING

Thursday, February 15, 2018

Day 2

8:00 a.m. to 2:56 p.m.

FDA White Oak Campus  
Building 31 Conference Center  
10903 New Hampshire Avenue  
Silver Spring, Maryland

**Meeting Roster**

**DESIGNATED FEDERAL OFFICER (Non-Voting)**

**Moon Hee V. Choi, PharmD**

Division of Advisory Committee and Consultant

Management

Office of Executive Programs, CDER, FDA

**ANESTHETIC AND ANALGESIC DRUG PRODUCTS ADVISORY**

**COMMITTEE MEMBERS (Voting)**

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Clinical Pharmacy Specialist

Department of Pharmacy

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Tampa, Florida

**Jeffrey L. Galinkin, MD, FAAP**

Professor of Anesthesiology and Pediatrics

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Medical Safety Officer

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1     **Jennifer G. Higgins, PhD**

2     *(Consumer Representative)*

3     Director of Research & Policy

4     Association of Developmental Disabilities

5     Providers (ADDP)

6     Framingham, Massachusetts

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8     **Ronald S. Litman, DO**

9     Professor of Anesthesiology & Pediatrics

10    Perelman School of Medicine

11    University of Pennsylvania

12    Attending Anesthesiologist

13    The Children's Hospital of Philadelphia

14    Medical Director, Institute for Safe Medication

15    Practices

16    Philadelphia, Pennsylvania

1 **Mary Ellen McCann, MD, MPH**

2 *(Acting Chairperson)*

3 Associate Professor of Anesthesia

4 Harvard Medical School

5 Senior Associate in Anesthesia

6 Boston Children's Hospital

7 Boston, Massachusetts

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9 **Abigail B. Shoben, PhD**

10 Associate Professor, Division of Biostatistics

11 College of Public Health

12 The Ohio State University

13 Columbus, Ohio

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15 **Kevin L. Zacharoff, MD, FACIP, FACPE, FAAP**

16 Faculty and Clinical Instructor

17 Pain and Medical Ethics

18 State University of New York Stony Brook School of

19 Medicine, Stony Brook, New York

20 Ethics Committee Chair

21 St. Catherine of Siena Medical Center

22 Smithtown, New York

**TEMPORARY MEMBERS (Voting)**

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Professor, Department of Anesthesiology and  
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**Padma Gulur, MD**

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Department of Anesthesiology  
Duke University  
Durham, North Carolina

**Laura D. Porter, MD**

*(Patient Representative)*  
Cancer Survivor Independent Patient Advocate  
Washington, District of Columbia

1     **ACTING INDUSTRY REPRESENTATIVE TO THE ANESTHETIC**  
2     **AND ANALGESIC DRUG PRODUCTS ADVISORY COMMITTEE**

3     **(Non-Voting)**

4     **Michele Hummel, PhD, RPh**

5     *(Acting Industry Representative)*

6     Pharmacist

7     Moss Rehab Einstein Healthcare Network

8     Elkins Park, Pennsylvania

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10    **FDA PARTICIPANTS (Non-Voting)**

11   **Sharon Hertz, MD**

12    Director

13    Division of Anesthesia, Analgesia and Addiction

14    Products (DAAAP)

15    Office of Drug Evaluation II (ODE-II)

16    Office of New Drugs (OND), CDER, FDA

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18   **Rigoberto Roca, MD**

19    Deputy Division Director

20    DAAAP, ODE-II, OND, CDER, FDA

1     **Alla Bazini, MD**

2     Medical Officer

3     DAAAP, ODE-II, OND, CDER, FDA

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6     Statistics Team Leader

7     Division of Biometrics II

8     Office of Biostatistics (OB)

9     Office of Translational Sciences (OTS)

10    CDER, FDA

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12    **Yun Xu, PhD**

13    Clinical Pharmacology Team Leader

14    Division of Clinical Pharmacology II

15    Office of Clinical Pharmacology (OCP)

16    OTS, CDER, FDA



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1       going on out there already, to take this and try  
2       and figure out what blocks this is helpful for and  
3       worth the money, frankly.

4               DR. McCANN: Are there any more comments on  
5       question number 1?

6               (No response.)

7               DR. McCANN: My task is to summarize a  
8       question that's been all over the map here. The  
9       question is what efficacy data are necessary to  
10      adequately evaluate the benefit of EXPAREL for  
11      nerve block? Discuss whether active comparator  
12      arms should be included in future efficacy studies  
13      of EXPAREL. I think the majority of the committee  
14      felt that it would be preferable to include a  
15      comparator arm but not absolutely necessary.

16              For the second part, discuss any  
17      circumstances where placebo-controlled studies  
18      alone are adequate to evaluate the efficacy of  
19      EXPAREL, Dr. Zacharoff commented that it's almost  
20      impossible to do in post-surgical patients,  
21      patients that are having pain, but others pointed  
22      out that as long as you demonstrate efficacy,